SAFETY DATA SHEET

BONIVA(R) F. C. Tablets 150 mg

SECTION 1. IDENTIFICATION

Product name : BONIVA(R) F. C. Tablets 150 mg
Product code : RO200-5450/F07
Common name(s), synonym(s) of the substance : BONVIVA Film Coated Tablets BONIVA F.C. Tablets

Manufacturer or supplier's details
Company name of supplier : Genentech, Inc.
Address : 1 DNA Way
South San Francisco, CA 94080
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone number : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Skin corrosion : Category 1B
Serious eye damage : Category 1
Carcinogenicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H314 Causes severe skin burns and eye damage. H351 Suspected of causing cancer. H373 May cause damage to organs through prolonged or
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Version 2.1  Revision Date: 11-16-2021  Date of last issue: 03-03-2020

Date of first issue: 06-10-2017

Repeated exposure.

Precautionary Statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibandronate</td>
<td>138926-19-9</td>
<td>36.3</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
<td>35.0</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>12.9</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>4.8</td>
</tr>
<tr>
<td>Octadecanoic acid</td>
<td>57-11-4</td>
<td>1.9</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>1.8</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-</td>
<td>25322-68-3</td>
<td>0.5</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice:
- Move out of dangerous area.
- Consult a physician.
- Show this material safety data sheet to the doctor in attendance.
- Do not leave the victim unattended.

If inhaled:
- Move to fresh air.
- If unconscious, place in recovery position and seek medical advice.
- If symptoms persist, call a physician.

In case of skin contact:
- Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
- If on skin, rinse well with water.
- If on clothes, remove clothes.

In case of eye contact:
- Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
- In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Continue rinsing eyes during transport to hospital.
- Remove contact lenses.
- Protect unharmed eye.
- Keep eye wide open while rinsing.
- If eye irritation persists, consult a specialist.

If swallowed:
- Keep respiratory tract clear.
- Do NOT induce vomiting.
- Do not give milk or alcoholic beverages.
- Never give anything by mouth to an unconscious person.
- If symptoms persist, call a physician.
- Take victim immediately to hospital.
- Rinse mouth with water.

Most important symptoms and effects, both acute and delayed:
- Causes serious eye damage.
- Suspected of causing cancer.
- May cause damage to organs through prolonged or repeated exposure.
- Causes severe burns.

Notes to physician:
- The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: High volume water jet

Specific hazards during fire fighting: Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products: In case of fire hazardous decomposition products may be produced such as:
- Nitrogen oxides (NOx)
- Oxides of phosphorus
- Carbon monoxide
- Carbon oxides

Further information: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Avoid exposure
- Use personal protective equipment.
- Avoid dust formation.
- Avoid breathing dust.

Environmental precautions: Prevent product from entering drains.
- Prevent further leakage or spillage if safe to do so.
- If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up: Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Avoid dust formation.
- Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling: Avoid formation of respirable particles.
- Do not breathe vapors/dust.
- Avoid exposure - obtain special instructions before use.
- Avoid contact with skin and eyes.
- For personal protection see section 8.
- Smoking, eating and drinking should be prohibited in the application area.
- Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage: Keep container tightly closed in a dry and well-ventilated
place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.

Storage temperature : Protected from heat and light
Protect from moisture.

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Stainless steel, Polyethylene bag in metal drum, glass, Blister packages

---

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibandronate</td>
<td>138926-19-9</td>
<td>IOEL</td>
<td>0.002 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td>Octadecanoic acid</td>
<td>57-11-4</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total)</td>
<td>10 mg/m3</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>TWA</th>
<th>10 mg/m³ (Titanium dioxide)</th>
<th>ACGIH</th>
</tr>
</thead>
</table>

**Predicted No Effect Concentration (PNEC):**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibandronate</td>
<td>Surface waters</td>
<td>0.39 µg/l</td>
</tr>
</tbody>
</table>

Remarks:
Based on acute data

**Engineering measures**
No data available

**Personal protective equipment**

Respiratory protection:
In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

Hand protection

<table>
<thead>
<tr>
<th>Material</th>
<th>Break through time</th>
<th>Glove thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrile rubber</td>
<td>&gt; 30 min</td>
<td>&gt; 0.11 mm</td>
</tr>
</tbody>
</table>

In case of full contact:

<table>
<thead>
<tr>
<th>Material</th>
<th>Break through time</th>
<th>Glove thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>butyl-rubber</td>
<td>&gt; 480 min</td>
<td>&gt; 0.4 mm</td>
</tr>
</tbody>
</table>

Remarks:
Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection:
Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection:
Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures:
Instruction of employees mandatory

Hygiene measures:
When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance:
tablet

Color:
white, off-white
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Self-ignition</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**SECTION 10. STABILITY AND REACTIVITY**

- **Reactivity**: No dangerous reaction known under conditions of normal use.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous decomposition**: No decomposition if stored and applied as directed.
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Date of last issue: 03-03-2020
Date of first issue: 06-10-2017

Incompatible materials: No data available
Hazardous decomposition products: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity
Method: Calculation method
Acute oral toxicity estimate: 2,142 mg/kg
Acute inhalation toxicity
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method
Acute inhalation toxicity estimate: 45.42 mg/l
Acute dermal toxicity
Method: Calculation method
Acute dermal toxicity estimate: > 5,000 mg/kg

Components:
Ibandronate:
Acute oral toxicity: LD50 Oral (Rat): 811 mg/kg

Lactose-1-Hydrate:
Acute oral toxicity: LD50 Oral (Rat): > 10,000 mg/kg
Acute inhalation toxicity: LD50 Oral (Rat): > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
Acute dermal toxicity: LD50 Dermal (Rabbit): > 2,000 mg/kg

Cellulose:
Acute oral toxicity: LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 Dermal (Rabbit): > 2,000 mg/kg

Octadecanoic acid:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.
Acute dermal toxicity: LD50 Dermal (Rat): > 5,000 mg/kg
Titanium oxide (TiO2):
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
   Method: OECD Test Guideline 425

Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation
Causes severe burns.

Product:
Remarks: Extremely corrosive and destructive to tissue.

Components:
Ibandronate:
Result: Causes burns.
Remarks: Extremely corrosive and destructive to tissue.

Octadecanoic acid:
Species: Rabbit
Exposure time: 24 h
Method: Patch Test 24 Hrs.
Result: No skin irritation

Titanium oxide (TiO2):
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye damage.

Product:
Remarks: May cause irreversible eye damage.

Components:
Ibandronate:
Remarks: May cause irreversible eye damage.

Octadecanoic acid:
Species: Rabbit
Result: No eye irritation

Titanium oxide (TiO2):
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Ibandronate:
Species: Guinea pig
Result: Did not cause sensitization on laboratory animals.

Titanium oxide (TiO2):
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Method: OECD Test Guideline 406

Germ cell mutagenicity
Not classified based on available information.

Components:

Ibandronate:
Genotoxicity in vitro: Test Type: in vitro test
Result: negative
Genotoxicity in vivo: Test Type: in vivo assay
Species: laboratory animal
Result: negative

Carcinogenicity
Suspected of causing cancer.

Components:

Ibandronate:
Species: laboratory animal
Result: negative

Lactose-1-Hydrate:
Remarks: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Cellulose:
Remarks: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Octadecanoic acid:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2) 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:
Ibandronate:
Effects on fertility : Species: laboratory animal
Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Species: laboratory animal
Result: No teratogenic effects., No embryotoxic effects.

STOT-single exposure
Not classified based on available information.

Components:
Lactose-1-Hydrate:
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:
Ibandronate:
Assessment : May cause damage to organs through prolonged or repeated exposure.

Lactose-1-Hydrate:
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Repeated dose toxicity

**Components:**

**Ibandronate:**
- **Species:** laboratory animal
- **NOAEL:** 0.15 mg/kg/w
- **Application Route:** i.v.
- **Exposure time:** 26 Weeks
- **Symptoms:** kidney toxicity
- **Remarks:** Chronic toxicity

Aspiration toxicity
Not classified based on available information.

**Components:**

**Ibandronate:**
No data available

**Lactose-1-Hydrate:**
No data available

---

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Ibandronate:**
- **Toxicity to fish:** LC50 (Cyprinus carpio (Carp)): 200 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - GLP: yes
  - LC0 (Cyprinus carpio (Carp)): 86 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - GLP: yes

- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 180 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - GLP: yes
  - NOEC (Daphnia magna (Water flea)): 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - GLP: yes

- **Toxicity to algae/aquatic plants:** ErC50 (Desmodesmus subspicatus (green algae)): 0.390 mg/l
  - Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): 0.218 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration

NOEC (Desmodesmus subspicatus (green algae)): 0.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no
Remarks: nominal concentration

ErC50 (Selenastrum capricornutum (green algae)): 4.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

EyC50 (Selenastrum capricornutum (green algae)): 1.4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

NOEC (Selenastrum capricornutum (green algae)): 0.22 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms: (activated sludge): 41.5 mg/l
Exposure time: 28 d
Test Type: aerobic
Method: OECD Test Guideline 301B
GLP: yes
Remarks: no adverse influence on substrate biodegradation

NOEC (activated sludge): 1,300 mg/l
Exposure time: 5 h
Test Type: Growth inhibition
GLP: no
Remarks: Barely inhibitory on aerobic bacterial reproduction (activated sludge)

Lactose-1-Hydrate:

Toxicity to fish: LC50: > 100 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity): > 1 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity: This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.

Toxicity Data on Soil: Not expected to adsorb on soil.

Other organisms relevant to the environment: No data available

**Cellulose:**

**Ecotoxicology Assessment**

Acute aquatic toxicity: This product has no known ecotoxicological effects.

Chronic aquatic toxicity: This product has no known ecotoxicological effects.

**Titanium oxide (TiO2):**

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
  - Exposure time: 96 h
  - Test Type: static test
- LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
  - Exposure time: 96 h
  - Test Type: semi-static test
  - Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
- LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
  - Exposure time: 48 h
  - Test Type: static test
  - Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Test Type: static test
  - Method: OECD Test Guideline 201
- EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
  - Exposure time: 72 h
  - Method: ISO 10253
- NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
  - Exposure time: 72 h
  - Method: ISO 10253

**Ecotoxicology Assessment**

Toxicity Data on Soil: Not expected to adsorb on soil.

Other organisms relevant to the environment: No data available
Persistence and degradability

**Components:**

**Ibandronate:**
Biodegradability: Concentration: 41.5 mg/l
Result: Not readily biodegradable.
Biodegradation: < 10%
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

Concentration: 1,000 mg/l
Result: Not inherently biodegradable.
Biodegradation: < 10%
Exposure time: 28 d
Method: OECD Test Guideline 302B
GLP: no

**Octadecanoic acid:**
Biodegradability: Biodegradation: 44%

**Titanium oxide (TiO2):**
Biodegradability: Remarks: Not applicable

Bioaccumulative potential

**Components:**

**Ibandronate:**
Partition coefficient: n-octanol/water: Remarks: No data available

**Lactose-1-Hydrate:**
Partition coefficient: n-octanol/water: log Pow: -5.03

**Cellulose:**
Partition coefficient: n-octanol/water: Remarks: No data available

**Stearic acid:**
Partition coefficient: n-octanol/water: log Pow: 8.23

**Titanium dioxide:**
Partition coefficient: n-octanol/water: Remarks: No data available
Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life with long lasting effects.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : The product should not be allowed to enter drains, water courses or the soil. Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3261
Proper shipping name : CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S. (ibandronate mixture)
Class : 8
Packing group : III
Labels : 8

IATA-DGR
UN/ID No. : UN 3261
Proper shipping name : Corrosive solid, acidic, organic, n.o.s. (ibandronate mixture)
Class : 8
Packing group : III
Labels : Corrosive
Packing instruction (cargo aircraft) : 864
**SAFETY DATA SHEET**

**BONIVA(R) F. C. Tablets 150 mg**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>11-16-2021</td>
<td>03-03-2020</td>
<td>06-10-2017</td>
</tr>
</tbody>
</table>

- **Packing instruction (passenger aircraft):** 860
- **Environmentally hazardous:** yes

**IMDG-Code**
- **UN number:** UN 3261
- **Proper shipping name:** CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S. (Ibandronate mixture)
- **Class:** 8
- **Packing group:** III
- **Labels:** 8
- **EmS Code:** F-A, S-B
- **Marine pollutant:** yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation**

**49 CFR**
- **UN/ID/NA number:** UN 3261
- **Proper shipping name:** Corrosive solid, acidic, organic, n.o.s. (Ibandronate mixture)
- **Class:** 8
- **Packing group:** III
- **Labels:** CORROSIVE
- **ERG Code:** 154
- **Marine pollutant:** no

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**SECTION 15. REGULATORY INFORMATION**

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**

- Carcinogenicity
  - Specific target organ toxicity (single or repeated exposure)
  - Skin corrosion or irritation
  - Serious eye damage or eye irritation

**SARA 313**

- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
</tr>
</tbody>
</table>

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibandronate</td>
<td>138926-19-9</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

Maine Chemicals of High Concern
Product does not contain any listed chemicals

Vermont Chemicals of High Concern
Product does not contain any listed chemicals

Washington Chemicals of High Concern
Product does not contain any listed chemicals

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

<table>
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California Permissible Exposure Limits for Chemical Contaminants

<table>
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</tr>
</tbody>
</table>

The ingredients of this product are reported in the following inventories:

AIIC: Not in compliance with the inventory
This product contains the following components that are not on the Canadian DSL nor NDSL:

- Ibandronate
- non hazardous compounds

Not in compliance with the inventory:

- NZIoC
- ENCS
- ISHL
- KECI
- PICCS
- IECSC
- TCSI
- TSCA
- TSCI
- TSCA list
- No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.
SAFETY DATA SHEET

BONIVA(TM) F. C. Tablets 150 mg

Version 2.1
Revision Date: 11-16-2021
Date of last issue: 03-03-2020
Date of first issue: 06-10-2017

NFPA 704:

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/'" represents the absence of a chronic hazard.

Full text of other abbreviations:

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA P0: USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA: 8-hour time weighted average
OSHA Z-1 / TWA: 8-hour time weighted average

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2010